

EXHIBIT 35

EDMUND ELDER, JR.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

OREXO AB,

Plaintiff,

-vs-

Civil Action No. 3:11-cv-3788

MYLAN PHARMACEUTICALS INC.
and MYLAN INC.,

Defendants.

Video examination of EDMUND J. ELDER, JR.,

taken at the instance of Plaintiff, under and pursuant to

the Federal Rules of Civil Procedure, before

JESSICA R. WAACK, Certified Realtime Reporter, Registered

Diplomate Reporter, Certified Shorthand Reporter and

Notary Public in and for the State of Wisconsin, at

Perkins Coie, One East Main Street, Suite 201, Madison,

Wisconsin, on Wednesday, November 14, 2012, commencing at

10:52 a.m. and concluding at 2:57 p.m.

Job No. 55525

1 EDMUND ELDER, JR.

2 your opinion of what the term "ordered mixture"
3 means in the '910 patent?

4 A I believe I summarized that as part of -- yeah, as
5 what I said there.

6 Q Okay. And, now, I'm looking at paragraphs 26, you
7 said, right? 27 and 30?

8 A That's correct.

9 Q Right. When I look at those three paragraphs, I
10 don't see there references to any of the
11 specification of the '910 patent, right?

12 A Well, in 30 I refer to the claims of the patent.
13 And in 26 -- I mean, Nystrom is referred to in the
14 specification of the '910 patent. So it is
15 incorporated by reference, certainly.

16 Q So is it your --

17 A In --

18 Q -- your opinion --

19 MR. HOCHSTETLER: Errol. Errol, you
20 interrupted him. You did interrupt him.

21 BY MR. TAYLOR:

22 Q Is it your opinion that the ordered mixture in the
23 Nystrom patent is identical to the ordered mixture
24 in the '910 patent?

25 MR. HOCHSTETLER: Objection.

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2 THE WITNESS: I don't believe they're
3 identical, per se. I mean, they're -- the '910
4 patent refers to the ordered mixture in the
5 Nystrom patent.

6 And there are some differences, I
7 believe, that are pointed out elsewhere in the
8 expert report regarding differences between them
9 in terms of -- that the '910 patent actually
10 indicates that it's an improvement upon Nystrom.
11 And that '910 is focused on sublingual tablets as
12 opposed to Nystrom that does not talk about that.

13 And then, also, the bio/mucoadhesive is
14 not indicated specifically in the Nystrom patent
15 or application.

16 BY MR. TAYLOR:

17 Q Right. The '910 patent includes a bioadhesive in
18 the ordered mixture while Nystrom does not,
19 correct?

20 MR. HOCHSTETLER: Objection.

21 THE WITNESS: I believe, in general
22 terms, Nystrom just does not refer specifically to
23 bioadhesive -- or bio/mucoadhesive agent.

24 BY MR. TAYLOR:

25 Q And the '910 patent does?

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2 and construe a definition of the term.

3 Q I know. But you just said you had an
4 understanding of what it meant based on your
5 general experience. What was that understanding?

6 A I said I have a general understanding of the term
7 "treatment" in terms of how I've used it in my
8 practice of pharmacy, but I did not assess its
9 definition in the context of the patent.

10 Q Okay. What is that general understanding that you
11 have of the term "treatment" as you've used it in
12 the context of your practice of pharmacy?

13 A In pharmacy, the term "treatment" would be the use
14 of -- or the -- utilizing drugs to improve the
15 health of patients.

16 Q And there was another term that the parties
17 apparently have a disagreement on, and that is the
18 effective amount of at least one pharmaceutically
19 active agent. When you read that term in the
20 claims, did you understand what it meant?

21 A Again, I was not asked to give an opinion on that
22 and would not have an opinion on it without
23 assessing it further. And, I mean, I would have a
24 general understanding based on my involvement in
25 pharmacy practice.

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2 Q And, again, what is your general understanding of
3 the meaning of that term based on your experience
4 in pharmaceutical practice?

5 A I mean, certainly it's not, you know, relevant to
6 the interpretation within this patent, because I
7 haven't asked -- been asked to do that.

8 But it would be -- the effective amount
9 would be the amount that would provide a
10 therapeutic effect.

11 Q Now let's go back to your declaration. And on
12 page 31 -- and we discussed this briefly a few
13 months ago when we were talking about your
14 understanding of the '910 patent.

15 A Where are you directing me again?

16 Q Paragraph 31.

17 A Paragraph 31.

18 MR. HOCHSTETLER: Objection.

19 BY MR. TAYLOR:

20 Q And you mentioned in that paragraph that the '910
21 patent states that it is an improvement upon the
22 prior art ordered mixture as described in Nystrom.
23 Do you see that?

24 A Yes.

25 Q Then you go on to point out two differences that

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2 Q I'm right -- I'm reading that correct?

3 MR. HOCHSTETLER: No, you're not.

4 MR. TAYLOR: Please don't interrupt me.

5 It's not an objection to say I'm not reading this.

6 I mean, it's just improper. Stop it.

7 MR. HOCHSTETLER: Please read it

8 accurately.

9 BY MR. TAYLOR:

10 Q Will you answer my question?

11 A What was your question?

12 Q You state that the '910 patent states that it's an
13 improvement over the Nystrom prior art ordered
14 mixture, right?

15 A I indicate that the '910 patent indicates that
16 it's an improvement upon the prior art ordered
17 mixture as described in Nystrom.

18 Q Right. Now, was Nystrom the first reference to
19 describe an ordered mixture?

20 A I don't recall if it was the first reference or
21 not.

22 Q Do you know whether there was such a thing as an
23 ordered mixture before it was mentioned by Nystrom
24 in this -- the Nystrom publication?

25 A Meaning, in general terms, ordered mixture is not

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2 a term that's used commonly in pharmaceutical
3 formulations.

4 We typically would deal with random
5 mixtures. And so -- I mean, I haven't studied
6 extensively the literature as to where the term
7 originated.

8 Q Well, do you know whether the term "ordered
9 mixture" was used by others prior to Nystrom in
10 the '725 Nystrom publication?

11 A Off the top of my head, I don't know if it was
12 used prior to that. I know there are some other
13 references regarding ordered mixtures and related
14 terms, but I don't know when they came out as
15 compared to when Nystrom was filed.

16 Q So, in your opinion, you relied on the ordered
17 mixture in Nystrom as the definition of an ordered
18 mixture?

19 A The patent specifically refers to that as an
20 ordered mixture on which it provides some
21 improvement.

22 Q Okay. Where --

23 A So it is part of --

24 Q Where is that in the patent?

25 MR. HOCHSTETLER: I object to your

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2 about the, "Still further, that the composition
3 comprises an ordered mixture of one or more
4 bioadhesive, mucoadhesive substances coated with
5 the pharmaceutically active agent in a fine
6 particulate form."

7 And then it goes on from there into the
8 section that we talked about regarding Nystrom.

9 BY MR. TAYLOR:

10 Q Now, does this term "ordered mixture" have an
11 ordinary meaning outside of the Nystrom reference
12 or the '910 patent?

13 A As I indicated earlier, I believe that the term is
14 not used often in the -- in pharmaceutical
15 formulations. We typically use random mixtures,
16 which are very different.

17 Q But that's actually not my question. Does it have
18 an ordinary meaning?

19 MR. HOCHSTETLER: Objection.

20 THE WITNESS: You mean in terms of
21 the -- interpreting the patent, we need to use the
22 information that's provided in the specification.

23 BY MR. TAYLOR:

24 Q Yeah, I know that. But my question is: Does the
25 term have an ordinary meaning? Yes or no.

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2 understood that ordered mixing wasn't necessarily
3 limited to an active ingredient and a carrier,
4 correct?

5 MR. HOCHSTETLER: Objection.

6 THE WITNESS: I mean, this -- like I
7 said, it's the introduction of the concept, and
8 it's a theoretical assessment.

9 And, in fact, they say that it -- not
10 that these are absolute processes, but that it's
11 how it may be possible, how such processes are
12 possible.

13 BY MR. TAYLOR:

14 Q Is it your -- is it your view as you sit here
15 today that ordered mixtures are limited to only
16 mixtures of active ingredients and carriers?

17 MR. HOCHSTETLER: Objection.

18 THE WITNESS: In the -- in the whole
19 world of things, they aren't necessarily limited;
20 however, in terms of the interpretation of the
21 '910 patent, it specifically indicates how they're
22 to be used.

23 BY MR. TAYLOR:

24 Q And in the '910 patent, there is a provision for
25 including the bioadhesive in the ordered mixture,

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2 right?

3 A The claim of bioadhesive agent is part of the '910
4 patent.

5 Q In the ordered mixture?

6 A That's correct.

7 Q Now, when you read the patent -- and I assume you
8 read it as a person of ordinary skill in the art
9 at the time of the filing would have read the
10 patent, right?

11 A I read it as to whom the patent was directed at
12 the time it was filed.

13 Q And the patent is directed to a person of ordinary
14 skill, correct?

15 A It's directed to a formulator with a certain
16 amount of experience.

17 Q Right. And that is what we call the person of
18 ordinary skill in the art. Do you understand
19 that?

20 A That is a legal term, I guess.

21 Q Okay.

22 A But, I mean, I look at where is the patent
23 directed in terms of the claim construction.

24 Q Right. And when you read the patent, did you
25 conclude that a person of ordinary skill, this

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2 person that you mentioned, reading the patent,
3 would have been able to make an ordered mixture of
4 the materials described in the patent?

5 A I believe my assessment of the patent is that,
6 yeah, a formulator should be able to reduce it to
7 practice.

8 Q Now, one of the things that the patent talks about
9 is ensuring that the bioadhesive agent is adhered
10 to the surfaces of the carrier, right?

11 A It talks about that, yes.

12 Q And one of the ways to do that is to create an
13 ordered mixture, correct?

14 A That's part of the definition of the ordered
15 mixture is that the drug as well as the bio --
16 mucobioadhesive is adhered to the surface of the
17 carrier particle.

18 Q And the bioadhesive is -- well, strike that.

19 Now, have you ever had the occasion to
20 prepare an ordered mixture yourself?

21 A I believe the work I did for my doctoral
22 dissertation is similar to what's being described
23 as an ordered mixture. I did not use that term in
24 any way during the time.

25 But, basically, I was trying to get a

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2 layered coating of a hydrophobic material on the
3 surface of drug particles.

4 Q And what processes did you use to get that
5 material in a layered coating on these materials?

6 A I used a dry mixing process with varying levels of
7 the coating material to see what theoretical
8 amounts were required to provide adequate
9 controlled release in this particular instance.

10 Q Are there various methods that a formulator can
11 use to prepare an ordered mixture?

12 MR. HOCHSTETLER: Objection.

13 THE WITNESS: In the concept of ordered
14 mixing, as it's described, is really just a
15 mixing -- or, I guess, using an ordinary mixing
16 process to get the particles to adhere to the
17 surface.

18 BY MR. TAYLOR:

19 Q Uh-huh. I mean, are there other ways to do that,
20 apart from using an ordinary mixing process?

21 MR. HOCHSTETLER: Objection.

22 THE WITNESS: There -- the formulator
23 has a number of processes available. Whether they
24 would achieve an ordered mixture or not would
25 require sufficient experimentation to be able to

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2 determine that.

3 BY MR. TAYLOR:

4 Q Now, when you looked at the '910 patent and the
5 definition of "ordered mixture," was that ordered
6 mixture in the patent process dependent?

7 And by that, you know, I don't mean to
8 be confusing. Would it matter how the formulator
9 made that ordered mixture; if he used one of
10 these, you know, various procedures that you just
11 mentioned to come to --

12 A As I indicated previously, most mixing that's done
13 to prepare pharmaceutical formulations is a random
14 type of mixing.

15 Q Uh-huh.

16 A And so it's not routine that one tries to achieve
17 an ordered mixture.

18 Q Yeah, I know. But my question was a little
19 different than that.

20 Someone makes an ordered mixture, but
21 they use something other than a dry mixing
22 process. Would that matter in your interpretation
23 of the '910 patent?

24 A Anytime one -- you know, in the formulation area,
25 it's very difficult to separate formulation and

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2 Q And then in the real world, that ordered mixture
3 would be tableted with other tableted excipients,
4 right?

5 A I think the composition could include the
6 tableting as well.

7 Q Right. The ordered mixture could include the
8 tableting excipients as well?

9 A No. The ordered mixture is specific to the
10 bio/mucoadhesive agent, the pharmaceutically
11 active agent and the carrier particles in terms of
12 the mixture. That can then be incorporated into
13 the overall composition being the tablet.

14 Q Okay. That's, I think, what I meant. I think
15 we're saying the same thing.

16 Now, when this claim talks about
17 essentially water-free, what's it referring to?

18 A It's referring to the composition of the ordered
19 mixture being essentially water-free.

20 Q Okay. Do those other things that go into the
21 pharmaceutical composition also need to be
22 essentially water-free?

23 A In the event that they're not, they could impact
24 as to whether you have an ordered mixture anymore.

25 Q So is that a yes?

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2 of ordinary skill in the art would appreciate that
3 microcrystalline cellulose does not exhibit
4 bio/mucoadhesive properties." Do you see that?

5 A Yes.

6 Q And do you agree with that statement?

7 A Yes, I do.

8 Q And it goes on to say that, "While
9 microcrystalline cellulose is in the
10 specification, that the applicants have amended
11 the specification and the claims to correct this
12 obvious error"?

13 MR. HOCHSTETLER: Objection.

14 BY MR. TAYLOR:

15 Q Do you see that? Do you see that?

16 A Yes. They amended the claim to remove
17 microcrystalline cellulose.

18 Q Now, did you find an amendment to the claims or
19 specification where the parties -- where the
20 inventors removed polyvinylpyrrolidone as a
21 bioadhesive agent?

22 A I don't believe they had it in there. I mean,
23 it's not in there as a mucobioadhesive, so it
24 wasn't there to remove in that perspective.

25 But it's certainly not utilized in that

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2 way. And it's also included in their definition
3 of a disintegrant, which is its usual use.

4 Q Now, do you know the reasons why the inventors
5 argued that their invention, the '910 inventions,
6 were patentable over the Nystrom prior art?

7 A I don't recall the specifics on that.

8 Q Go to page 200 of the file history, ORM200. And
9 you see there is -- that is the second page of the
10 response after final rejection?

11 A Yes.

12 Q And I believe it's dated January 15, 2004?

13 A That's correct.

14 Q And you see at the bottom of page 200 going over
15 to 201, there is a discussion of what was noted
16 during an interview with the examiner regarding
17 Nystrom and its differences from the '910 patent.
18 Do you see that?

19 A So specifically you're referring to this
20 paragraph, the last paragraph --

21 Q Yeah, I'll tell -- I'll just --

22 A Okay.

23 Q -- try to orient you now. I'm referring to the
24 bottom of page 2 over into page 3, which is really
25 most of page 3. There's a discussion there of

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2 bio and mucoadhesive material, the claimed
3 composition enables the pharmaceutically active
4 agent to be absorbed in the mucosal lining of the
5 oral cavity? And I'm paraphrasing.

6 A I see that.

7 Q And you agree with that as a teaching of the '910
8 patent?

9 MR. HOCHSTETLER: Objection.

10 THE WITNESS: Well, here I believe the
11 composition they're referring to is the final
12 dosage form.

13 And the ordered units would be the
14 ordered mixture, which is described in the
15 previous sentence, which get dispersed to then
16 provide the absorption of the drug.

17 BY MR. TAYLOR:

18 Q Right. And that's provided because of the
19 inclusion of the bioadhesive agent in the ordered
20 mixture?

21 MR. HOCHSTETLER: Objection.

22 THE WITNESS: That's what the ordered
23 mixture is there to do is to provide both the
24 bioadhesive and the drug, which then holds the
25 drug in close -- in -- against the mucosal

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2 material.

3 BY MR. TAYLOR:

4 Q Now, it goes on to say in the next paragraph that,
5 "Nystrom," and I'm quoting here, "fails to teach a
6 bioadhesive and/or mucoadhesive component mainly
7 adhered to the surface of a carrier component."
8 Do you see that?

9 A Yes.

10 Q Would you agree with that?

11 A I believe that's correct. That's a difference
12 between the '910 and the Nystrom, yes.

13 Q Okay. Now, if you refer to the '910 patent. And
14 this Ac-Di-Sol component, right? it's used in '910
15 as both a disintegrant and a bioadhesive, right?

16 A Uh-huh. That's what they're saying in the '910
17 patent.

18 Q And in the '910 patent, it's formulated in such a
19 way that the Ac-Di-Sol is primarily adhered to the
20 surfaces of the carrier, right?

21 MR. HOCHSTETLER: Objection.

22 THE WITNESS: I mean, it's certainly
23 mixed in there with the carrier that has the drug
24 added to it as well.

25 BY MR. TAYLOR: